

INSTRUCTION MANUAL

1266.XIII

BrightStar illumination Unit



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TECHNOLOGY CREATED BY VISION

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TABLE OF CONTENTS

SECTION 1 – INTRODUCTION.....	4
INTENDED USE	4
SECTION 2 – UNPACKING AND INSTALLATION.....	5
PREPARING THE UNIT FOR USE	5
SECTION 3 – GENERAL SYSTEM DESCRIPTION.....	6
DESCRIPTION, CONTROLS AND FEATURES	6
SWITCHING ON	7
LAMP-ON INDICATOR	8
DISPLAY	8
INTENSITY CONTROL	8
FILTER SELECTION	9
FIBER CONNECTOR	9
SECTION 4 – PROFESSIONAL USERS INFORMATION.....	10
SELECTING THE ILLUMINATION LEVEL	10
APHAKE HAZARD FUNCTION (ISO 15752) AND ISO-UNITS	11
LIGHT INTENSITY AND LUMENS UNITS.....	12
SECTION 5 – SPECTRAL OUTPUT.....	13
SECTION 6 – SERVICE INSTRUCTIONS	14
LAMP REPLACEMENT	14
REPLACING THE FUSES.....	17
RECOMMENDED SPARE PARTS	17
PERIODICAL INSTRUCTIONS FOR PREVENTIVE INSPECTION AND MAINTENANCE.....	17
CLEANING THE ENDO-ILLUMINATOR.....	17
STERILIZATION OF KNOBS	18
RETURNING THE UNIT FOR SERVICE	19
SECTION 7 – SPECIFICATIONS.....	20
LABEL	21
ICONS USED.....	22
SECTION 8 – WARNINGS	24
ELECTRIC SHOCK HAZARD	24
EXPLOSION HAZARD	24
SECTION 9 – ELECTROMAGNETIC COMPATIBILITY (EMC)	25
SECTION 10 – WARRANTY.....	29
SECTION 11 – ACCESSORIES.....	30

Section 1 – Introduction

The D.O.R.C. Xenon BrightStar ophthalmic endo-illuminator is a high-intensity light source for launching light into two separate fiber-optic probes that are used for illumination of the eye during eye-surgery.

It contains a 75W Xenon source and optics to image the arc of this source onto two separate fiber outputs. The intensity and UV-cutoff wavelength of the two outputs can be controlled separately using four different UV-cutoff filters and an intensity control knob.

This manual provides the necessary information to understand and safely use and maintain the D.O.R.C. Xenon BrightStar.

Intended Use

The D.O.R.C. Xenon BrightStar endo-illuminator is intended to provide intraocular illumination during vitreo-retinal surgery. The Xenon BrightStar provides two light source outlets to use two illumination accessories simultaneously. The light output of the two outputs can be adjusted individually. The Xenon BrightStar will accept a wide range of D.O.R.C. fiber optic accessories.

Section 2 – Unpacking and installation

The Xenon BrightStar comes in a double carton box. Please check the box and its content for any significant damage. In case of doubt contact D.O.R.C. immediately (see section 6 on support).

The box should contain the following items:

1. The Xenon Bright Star endo-illuminator.
2. A mains cord for connecting the illuminator to the mains power.
3. A set of removable and sterilisable knobs already attached to the unit
4. This instruction manual

Note : The power cord used to connect the system to the wall outlet is shipped with systems for use in continental Europe only. For other countries a power cord with appropriate ratings and national safety agency approval must be used.

Preparing the Unit for Use

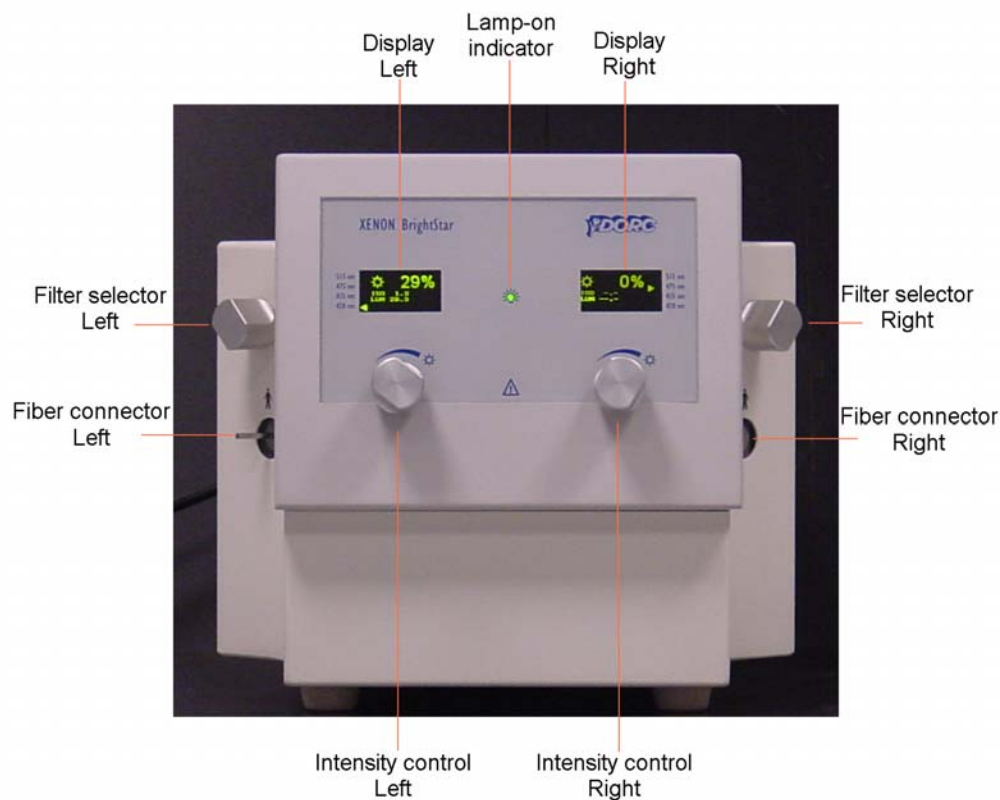
1. Place the Xenon BrightStar endo-illuminator onto a firm, smooth surface. This can be a table, shelf or the D.O.R.C. Associate Unit. Please note that the weight of the unit is approximately 15 kg and that the surface should support this weight.
2. Connect the mains cord to the endo-illuminator first before connecting it to the mains plug.
3. Remove all four knobs by pulling them from their shafts.
4. Sterilize the knobs following the description in section 6.
5. Place the sterilized knobs on the appropriate knob interfaces. The knob should click in position.

Section 3 – General System Description

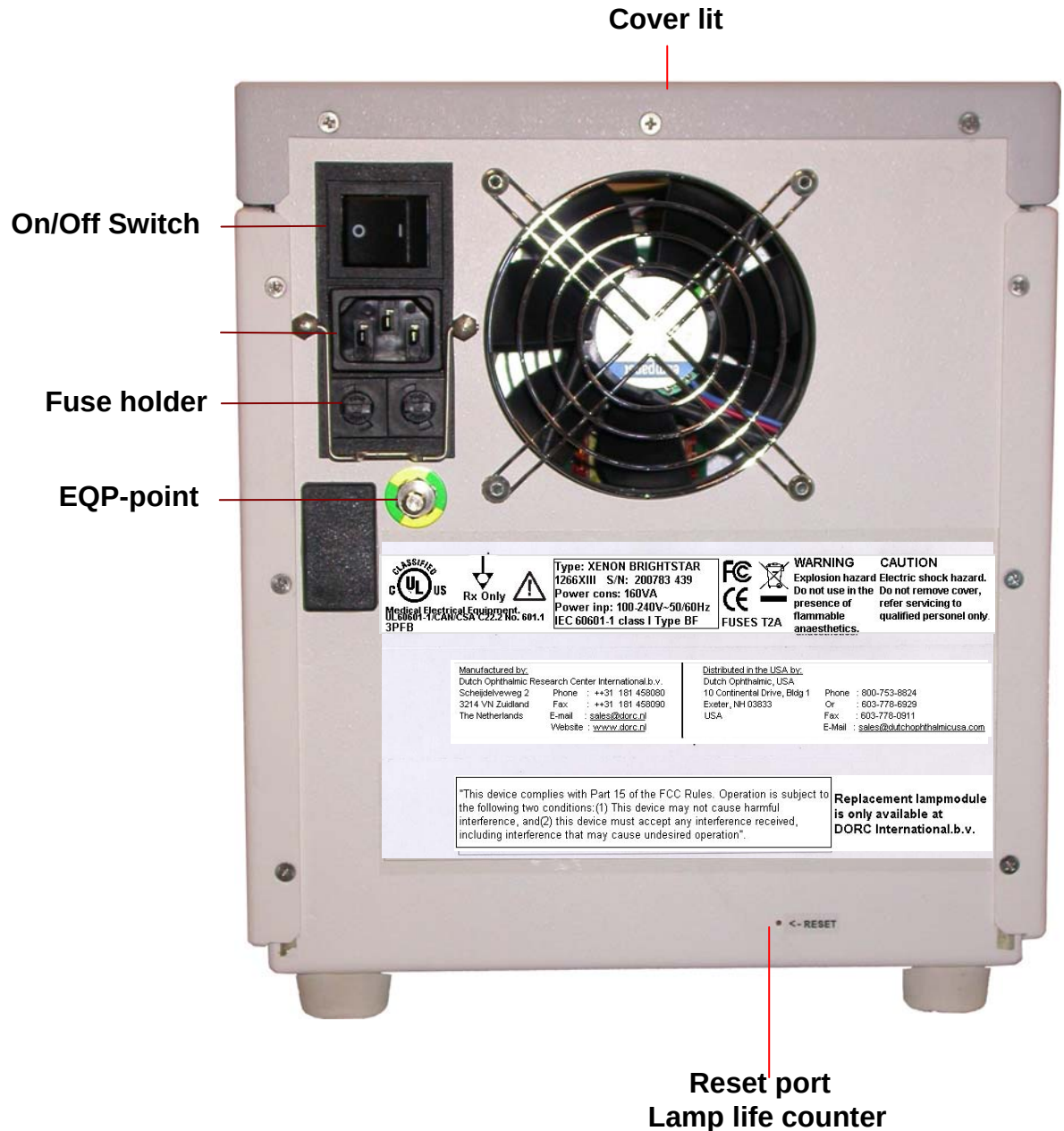
Description, controls and features

The D.O.R.C. Xenon BrightStar endo-illuminator contains a 75W short-arc Xenon lamp. Light of this lamp is collected by two sets of precision optics and imaged onto the fiber-optic entrances. With no fibers connected these entrances are automatically blocked for safety reasons.

Each of the two light paths has its own controls and display (see the figure below) and can be operated independently. The display and controls to the left of the unit are for the left fiber input; those on the right are for the right fiber input. We will discuss the features and controls of the endo-illuminator for one section.



D.O.R.C. BrightStar endo-illuminator - Front View.



D.O.R.C. BrightStar endo-illuminator - Rear View.

Switching on

The unit is switched on by pressing the on/off switch on the rear of the unit. Automatically the lamp is ignited. If the ignition is successful the lamp-symbol in between the displays will lighten. The displays will light to indicate that power is on and during several seconds both displays show the number of burning hours of the lamp and the software version.

Note that the rated lifetime of the light source is 400 hours. Replace the lamp before this number is reached. The motorized intensity control is initialized and will produce a humming sound while homing.

Lamp-on indicator

In between the displays a lamp-symbol will lighten if the Xenon lamp was ignited successfully. If it does not light within 5 seconds the Xenon lamp is probably defect and the display will indicate 'lamp error'. Refer to the lamp replacement description in section 6 for replacing the lamp module.

Display

The display presents the following information:

1. Upon power-up both displays show the number of burning hours of the lamp and the software version of the embedded software.
2. The display shows the intensity level in three different ways:
 - a. Percentage, ranging from 0 to 100%
 - b. Lumens, mainly depending on the connected fiber type (important parameters: diameter, tip form and fiber material)
 - c. ISO-values, depending on the connected fiber type and depending on the filter setting.
Lumens and ISO-values are discussed in more detail in section 4.
3. Filter pointer. This pointer points to the wavelength of the UV-cutoff filter that is selected.
4. Errors and messages:
 - a. Lamp error. In case of malfunction of the lamp this error is displayed
 - b. Incorrect barcode. May occur if the barcode on the fiber sleeve is missing or not detected.
 - c. Stepper time-out. Indicates malfunction of the intensity control.



Typical information presented on a display of the D.O.R.C. BrightStar endo-illuminator

Intensity control

The knob directly below the display controls the light intensity. When fully rotated counter clockwise (CCW) the intensity is set to zero. When fully rotated clockwise the intensity is set to a maximum. In between, the intensity is near linear with the knob setting and the actual intensity is presented in the display.

Important notes:

- It is good practice to turn the intensity knob always fully CCW before removing or inserting a fiber optic probe
- Always use the lowest possible intensity setting to minimize risk of eye damage to the patient. See also section 4.

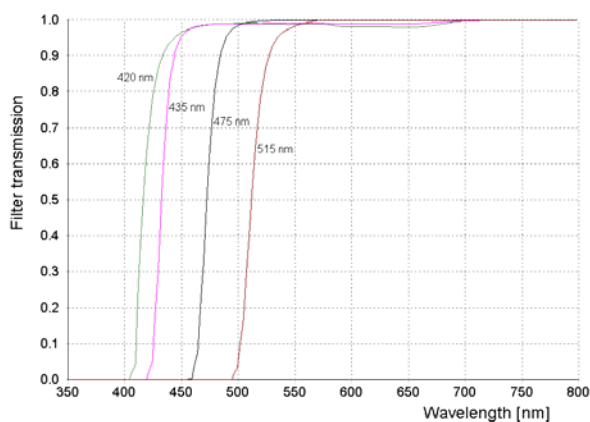
Filter selection

The D.O.R.C. Xenon BrightStar endo-illuminator has four UV-cutoff filters in each branch. These filters absorb hazardous UV-radiation and extend the time during which the light from the endo-illuminator can be safely used for surgery. The following filters can be selected by rotating the knob directly above the fiber entry:

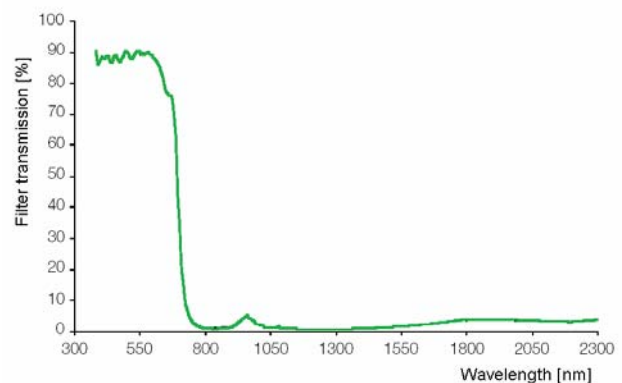
- 420 nm, blocking light with a wavelength shorter than 400nm
- 435 nm, blocking light with a wavelength shorter than 420nm
- 475 nm, blocking light with a wavelength shorter than 460nm
- 515 nm, blocking light with a wavelength shorter than 490nm

Besides these UV-cutoff filters, a fixed infra-red filter is present in the light path. This filter suppresses light with a wavelength longer than 700nm.

The characteristics of all filters are given in the figures below.



UV-cutoff filter characteristics



IR-cutoff filter characteristic

Use of a longer UV-cutoff wavelength will lower the level of hazardous UV-radiation and thus lower the ISO-value. See section 6 concerning the light output.

The D.O.R.C. BrightStar automatically displays the correct ISO and lumens values.

Fiber connector

The fiber entry is designed to accept D.O.R.C. fiber probes. Align the fiber sleeve with the opening and gently push the fiber in. You will notice a first barrier. This is the mechanism that blocks light when the fiber is retracted from the fiber entry. Push the fiber across this barrier. Near full insertion a second barrier will be noted. This is the mechanism to position the fiber tip precisely. Push the fiber across this last barrier until the fiber is fully inserted and encounters a last mechanical stop.

The sleeve of D.O.R.C. fiber probe has a bar code that contains information used by the Xenon BrightStar endo-illuminator to present accurate Lumen and ISO values and for automatic output limitation. These values depend on the type of fiber used.

Do not use other fibers than the D.O.R.C. fibers.

Section 4 – Professional users information

Selecting the illumination level

The Xenon BrightStar endo-illuminator is a high intensity light source for ophthalmic use and should be used with care to avoid eye-damage.

The following information is in major part taken from the International Standard "ophthalmic instruments - Endo-illuminators - fundamental requirements and test methods for optical radiation safety" ISO15752:2000(E) and adapted to the D.O.R.C. Xenon BrightStar endo-illuminator.

It is recommended that the illumination levels be set to the minimum level necessary to perform the surgical procedure. Young children, aphakes and persons with deceased eyes may be at higher risk. The risk may also be increased if the person being examined or operated has had any exposure with the same instrument or any other ophthalmic instrument using an intense visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

It is recommended that, when any component inside the endo-illuminator is changed or replaced, the output is measured according ISO15751.

The decision about the intensity of light level to use in any procedure shall be made on a case-by-case basis. In each case, the surgeon must make a risk-benefit judgment about the intensity of light to be used. Use of insufficient intensity may result in inadequate visualization and in adverse effects more serious than a retinal photic injury. Further, despite all efforts taken to minimize the risks of retinal damage from endo-illuminators, damage may still occur. Retinal photic injury is a possible complication of the need to use bright light to clearly visualize ocular structures during delicate ophthalmic surgical procedures.

Spectrally-weighted aphakic retinal irradiance, E_A , gives a measure of the potential hazard that exists for a beam of light to cause photochemical damage to the retina. The value stated for an endo-illuminator gives a measure of hazard potential when the instrument is operated at a maximum intensity.

The following information is intended to aid the surgeon in determining the potential risk. For instance, at an aphakic retinal irradiance level of 50mW/cm^2 , about 50 seconds irradiation of the retina would cause the retina exposure dose level to attain the recommended daily exposure limit used in occupational health. If the value were reduced to 25mW/cm^2 , twice as much time (i.e. 100 seconds) would be required to reach the recommended limit. It should be noted that there is a safety factor of about 10 built into the limit; hence, photo retinitis might be expected for an exposure time of $10 \times 100 \text{ s} = 1000 \text{ s}$ (about 17 minutes).

For the D.O.R.C. endo-illuminator an aphakic retinal irradiance level of 50mW/cm^2 is defined as 1 ISO-unit.

For the reference aphakic retinal irradiance of 50mW/cm^2 (or 1 ISO-unit), photoretinitis might be expected to occur in a total retinal exposure time of 8.5 minutes. The times calculated to exceed the limit or that expected for photoretinitis to occur are for an exposure to the uninterrupted beam at a particular point on the retina. Normal procedures, however, do not involve exposure to a single point on the retina. Procedures which involve movement of the light guide would be expected to extend the time before which photoretinitis might occur. Equally, interruption of the beam will similarly extend the safe operating time. Changing the

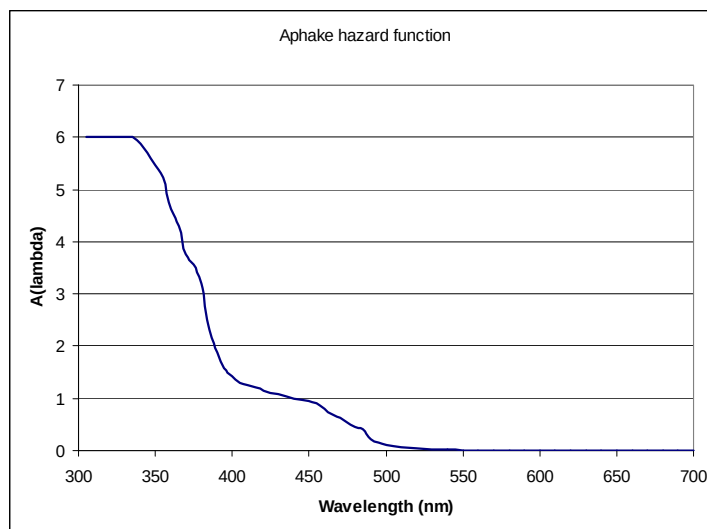
distance of the light guide from the retina will also significantly affect the risk factor; reducing the distance from 5 mm to 2 mm can increase the risk by as much as a factor of four times.

Changing the light guide, for example to one with a different numerical aperture from that for the original light guide, can change the optical radiation emissions from the distal end of the light guide. The D.O.R.C. endo-illuminator recognizes a D.O.R.C. light guide and automatically displays the correct amount of radiation at the distal end of the light guide, expressed in ISO-units. Using this information the surgeon can assess the relative change of potential risk by comparing the displayed ISO-units for the different types of light guides available.

For light guides with a flat emitting (i.e. non-focussing) aperture the numerical aperture provides an indication of the field of illumination on the retina. A numerical aperture of 0.5 will produce a field of illumination, the diameter of which is equal to approximately 2/3 the distance from the exiting aperture to the retinal surface. Thus, an endo-illuminator positioned 6 mm from the retina will produce a field diameter of approximately 4 mm. A larger numerical aperture will produce a larger field of illumination, whilst a smaller numerical aperture will produce a smaller field of illumination.

Aphake hazard function (ISO 15752) and ISO-units

High intensity light may induce phototoxic reactions that cause damage to the retina. The aphake hazard function is a weighting function that, convoluted with the spectral output of the source and integrated over the full wavelength range, gives the amount of *hazardous optical power* E_A produced by the endo-illuminator.

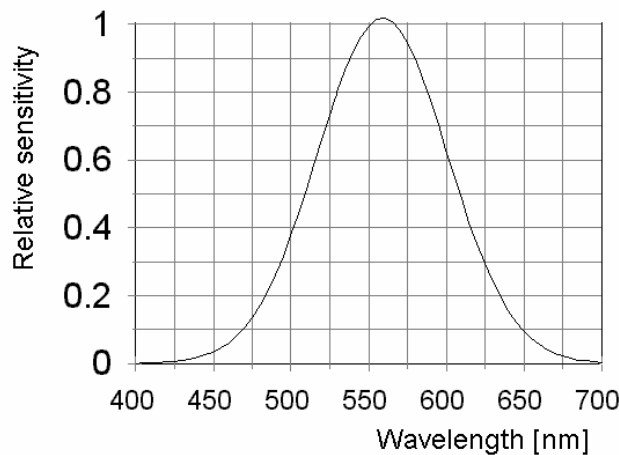


A hazardous optical power level of $50\text{mW}/\text{cm}^2$ is defined as 1 ISO-unit. It is measured at 5mm from the exiting aperture of the light guide using a 3 mm diameter circular aperture (refer to ISO15751:2000, Annex C). With this power level it is recommended to restrict surgery time to a maximum of 50 seconds. The safe surgery time is inversely proportional to the ISO-value. Thus, with a hazardous power level of 0.5 ISO-units safe surgery time may be doubled to 100 seconds.

The aphake function is substantial for shorter wavelengths. As a result UV-cutoff filters will reduce the hazardous optical power and the longer the cut-off wavelength, the lower the level of hazardous radiation. Using the 515nm filter minimizes the ISO-value and thus maximizes the available time for safe surgery.

Light Intensity and Lumens units.

Besides the hazardous output power, that should be kept as low as possible, the endo-illuminator should produce a maximum of useable light intensity. The figure below gives a graph of the photopic sensitivity of the eye under daylight conditions. The light intensity, denoted in units of Lumen, is the total output of the endo-illuminator calculated by convoluting the spectral output with the photopic curve and integrating the result over the full wavelength range.



The useful region in which the aphake function is low and the photopic function is high ranges from 500 to 650nm. The D.O.R.C. Xenon BrightStar provides a 515nm cutoff UV-filter that minimizes the aphakic hazard with little compromise to visual intensity.

Drawback of the 515nm filter is the yellow appearance of the light. Other UV-cutoff filters result in a more white appearance of the light at the cost of a higher ISO-value (i.e. more hazardous radiation).

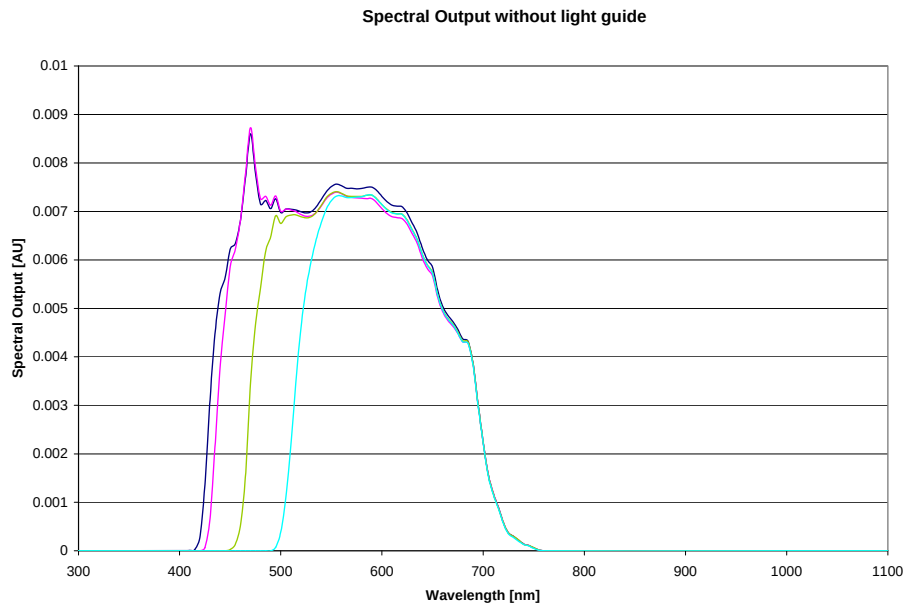
The displays of the D.O.R.C. Xenon BrightStar endo-illuminator shows the ISO and Lumens setting of the appropriate fiber output in combination with the attached D.O.R.C. fiber probe.

The intensity in Lumens units [lm] is only slightly dependent on the use of the UV-cutoff wavelength and independent of the shape of the light beam that emerges from the fiber probe.

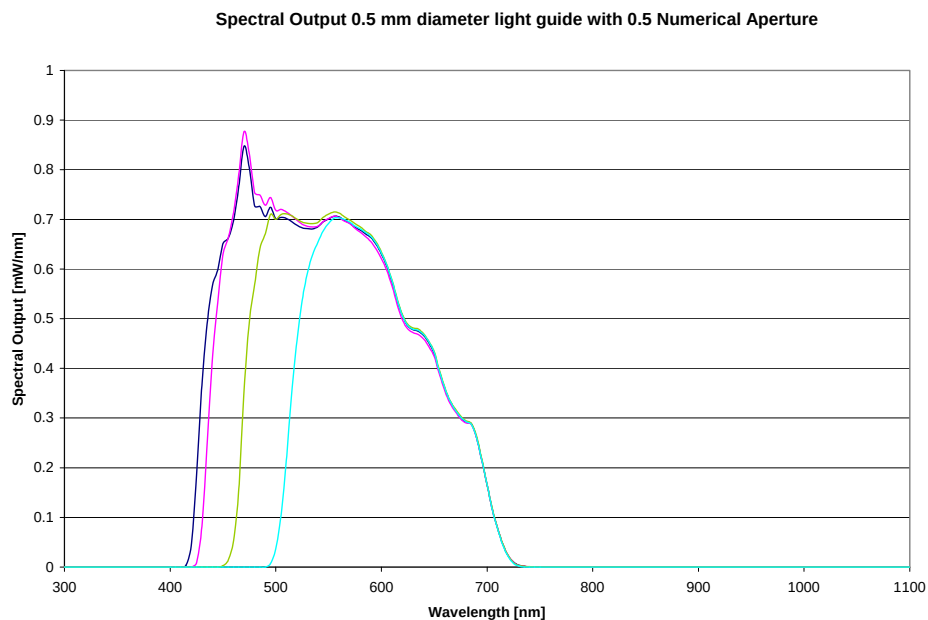
Besides on the UV-cutoff wavelength, the ISO-value strongly depends on the shape of the emerging light cone. Refer to the values shown in the display for the exact number of ISO-values.

Section 5 – Spectral output

The spectral output of the D.O.R.C. Xenon BrightStar unit for different UV-filter settings is shown in the figure below.



The spectral output of the D.O.R.C. Xenon BrightStar unit at maximum intensity and for different UV-filter settings, as measured with a D.O.R.C. fiber probe with a 0.5mm core and a numerical aperture of 0.5, is shown in the figure below.



Section 6 – Service Instructions

Lamp replacement

The rated lifetime of the Xenon lamp is 400 hours. Replace the lamp before this number is reached. After 400 hours the illumination will not be according equipment specification. When the lamp is used well beyond its specified lifetime (>800 hours) serious damage to the BrightStar is possible.



Warning !

- **The Xenon lamp and module used in this unit become very hot when the unit is operating. Before changing the lamp module, shut OFF the unit and allow at least 5 minutes for the module to cool down. Never touch a hot bulb with your bare fingers. Do not wear vinyl gloves, when working with a hot bulb.**
- **Lamp replacement should be performed by qualified personnel only.**
- **Wear protective eye-wear and gloves during removal and installation of the lamp.**

Caution !

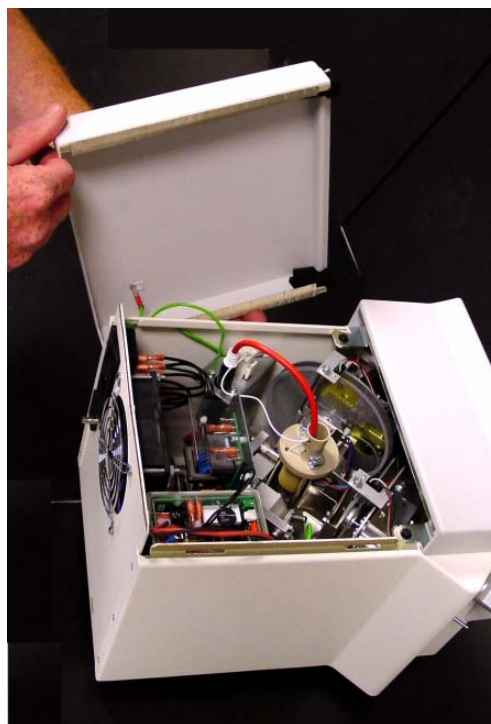
- **Do not touch the mirrors and lenses near the lamp module. Any fingerprints will reduce the amount of light produced by the unit. Remove any fingerprints using a lens cloth and alcohol.**
- **Never touch the glass portions of the lamp.**

The Xenon lamp is a pre-aligned module that comes in a transparent container. Replacement is done in the following steps:

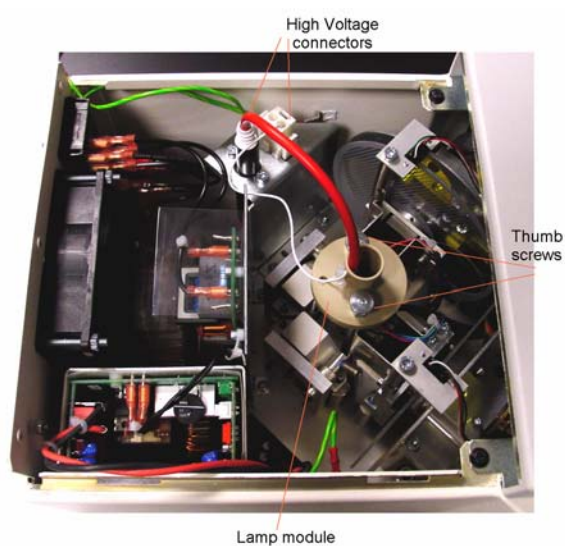
1. Switch the unit off.
2. Remove the power cord or power connection from the unit.
3. Wait for at least 5 minutes to allow the lamp to cool down.
4. Remove the cover lit of the endo-illuminator by removing three screws of the cover lit at the rear side using a Phillips screw driver and sliding the lit an inch backwards.
5. The lit can now be taken off. There is a grounding connection to the lit: Leave it connected to the lit.
6. Disconnect the two High Voltage connectors leading from the lamp module to the connector plate.
7. Fully unlock the two thumb screws that extent from the lamp module.
8. Now gently pull the lamp module from its socket, carefully take it out of the unit and put it aside in a safe place.



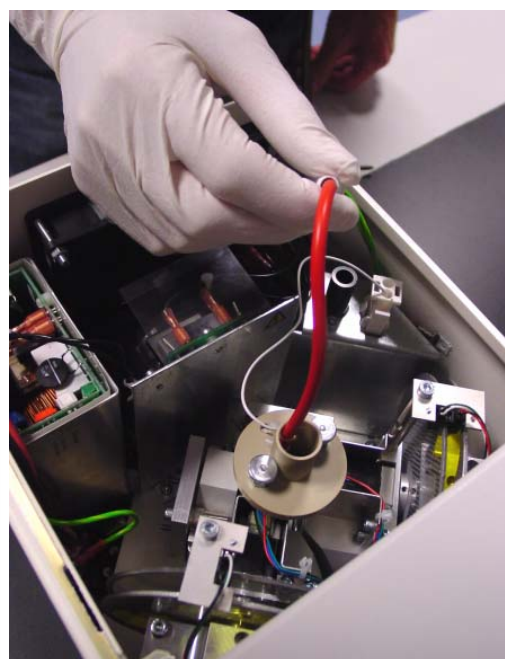
Step 4



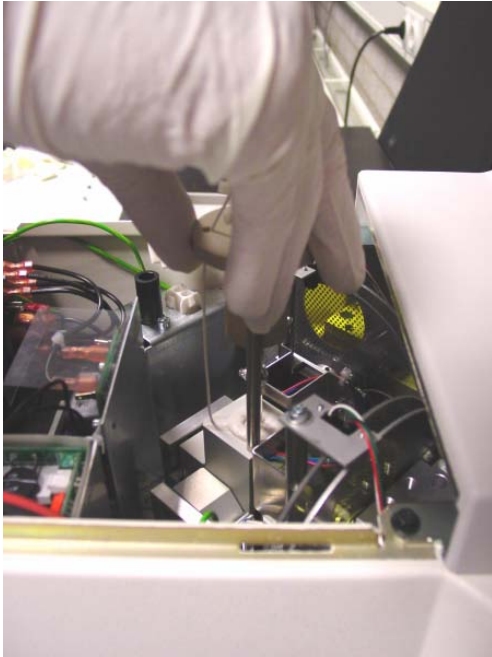
Step 5



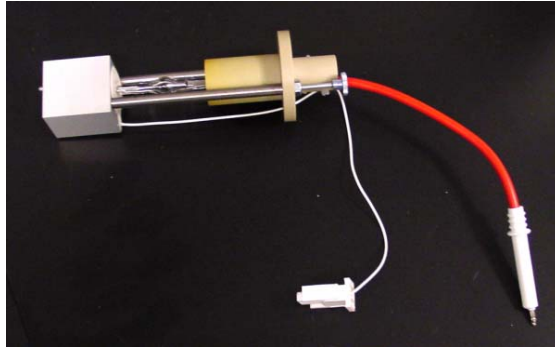
View inside the endo-illuminator



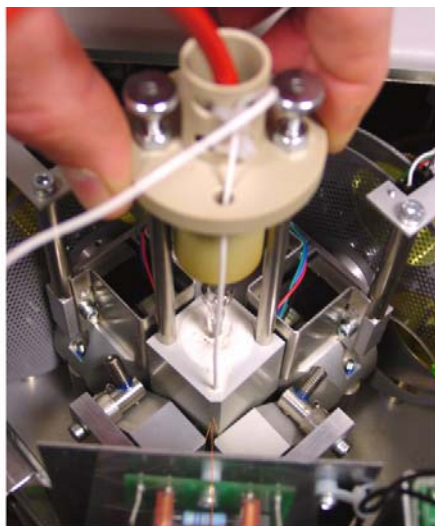
Step 6



Step 8



The lamp module



Rear side of unit
Beveled side of the lamp module

Step 10

9. Take the new lamp module from its protective container.
10. Watch the orientation of the lamp module. The bottom part has a beveled side that interfaces with shape of the socket in the endo-illuminator and should point to the rear of the unit.
11. Insert the lamp module in the unit and gently push it onto the socket.
12. Lock the module using the two thumb screws. Do not over tighten the screws.
13. Connect the two wires of the lamp module to the connector plate.
14. Put the cover lid back in place and fasten the lid using the three screws on the rear side.
15. Put the old lamp module in the protective container and dispose off properly. Refer to your local regulations.
16. Connect the power cord and restore the power connection.

17. Switch the unit on and wait for the displays to light up.
18. Now press the reset button that is accessible from the backside of the unit. This will reset the hour-counter of the lamp-module to zero.

Replacing the Fuses

1. Turn OFF the power switch on the back of the unit. Unplug the power cord.
2. The fuses are located on the rear of the unit, inside the black box at the point where the power cord is attached. The fuse cover has two tabs.
3. Remove the old fuses. Replace them with two new fuses of the same type :

Voltage	Fuse	Dimensions
230/240V	T2A slow-blow	5 x 20 mm.

The fuse type is also listed on the label on the rear of the unit.

4. Plug-in the power cord and turn ON the power switch on the rear of the unit.
5. **Important !** If the new fuses fail quickly, there may be something wrong with the unit. Call D.O.R.C. International b.v. for instructions.

Recommended Spare Parts

D.O.R.C. International b.v. recommends that you keep the following parts on hand. If a problem develops, this will allow you to return the unit to service quickly.

Part	Description
Xenon Lamp module	75W pre-aligned lamp module for D.O.R.C. Xenon BrightStar endo-illuminator
Fuse – 230/240V	T2A slow-blow

Periodical Instructions for preventive Inspection and maintenance

Periodical instructions for preventive inspection besides user or operator cleaning instructions:

Annual inspection: Inspect mains inlet, Equipotential connection and power cord for damages and insulation resistance.

Service manual on request available through your local distributor or D.O.R.C. International b.v.

Cleaning the endo-illuminator

Use a small amount of standard cleaner and a cotton cloth material to clean the external surfaces of the Xenon BrightStar endo-illuminator. Avoid ingress of cleaner fluids into the unit by just moistening the cotton cloth.

DO NOT use acetone to clean any part of endo-illuminator since this will damage the front and coating of the unit.

Sterilization of knobs

The removable and sterilisable knobs of the D.O.R.C. endo-illuminator should be sterilized for the next surgical procedure using any of the following methods:

100% ETO cycles

Concentration ETO: 625 ± 75 mg/l

Temperature: 37°C - 47°C

Exposure time: 3 - 4 hours

Humidity: 70% RH minimum

Steam autoclaving

<i>Sterilizer type:</i>	Gravity displacement	Prevacuum
<i>Sample config.:</i>	wrapped	wrapped
<i>Temperature:</i>	121°C to 123°C	132 °C to 135°C
<i>Exposure time:</i>	15 to 30 minutes	3 to 4 minutes

"Flash" autoclaving

<i>Sterilizer type:</i>	Gravity displacement	Prevacuum
<i>Sample config.:</i>	unwrapped	unwrapped
<i>Temperature:</i>	132°C	132°C
<i>Exposure time:</i>	3 minutes	3 minutes

Above mentioned sterilization cycles represent industry standards and should be capable of producing a sterile knob. Due to variations in sterilization equipment and device bioburden in clinical use, D.O.R.C. is not able to provide specific cycle parameters. It is the **responsibility of each user** to perform a validation and verification of the sterilization cycle to ensure an adequate sterility assurance level for our products.

Returning the Unit for Service

1. Before returning the unit to D.O.R.C. International b.v. for service, please contact the Service Department :

D.O.R.C. International b.v.
Attn.: Service Department
Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

Phone : ++31-181-458080
Fax : ++31-181-458090
E-mail : sales@dorc.nl
Web-site : www.dorc.nl

2. Please try to protect the unit as much as possible during shipping. It is best to use the original packaging if it is available.

Section 7 – Specifications

GENERAL

Apparatus	:	BrightStar endo-illuminator
Type	:	1266 XIII
Light source	:	75W short arc Xenon, ozone free
Weight	:	15 Kg.
Dimensions	:	350 x 250 x 300mm
Medical product class	:	Class I, Type BF
Protection class	:	IPX0

INPUT

Mains supply	:	100VAC / 240VAC 50/60Hz
Fuses	:	2 x at 230VAC T2A slow-blow
Power consumption	:	160VA

OUTPUT

Maximum spectral output range	:	410-700nm
Maximum intensity level (20Ga fibre)	:	80 lm
Numerical aperture	:	up to NA=0.6

ENVIRONMENT :

Operation :

- a) An ambient temperature range of +10°C to +40°C.
- b) A relative humidity range of 10% to 85% without condensation.
- c) An atmospheric pressure range of 700 hPa to 1060 hPa.

Transport & Storage Conditions :

- a) An ambient temperature range of -40°C to 70°C.
- b) A relative humidity range of 10% to 100% including condensation.
- c) An atmospheric pressure range of 500 hPa to 1060 hPa.

DISPOSAL :

The user (owner) of the DORC Xenon BrightStar endo-illuminator is responsible for a safe and environmental conform disposal of the BrightStar endo-illuminator after its service life.

Do not dispose of as a normal domestic refuse. In order to prevent environmental risks, please address yourself to specialized companies for the disposal of the device and of all its accessories.

Please note that the product does not contain any dangerous materials. Its disposal will not damage the environment and will not put at risk staff charged with the disposal itself. As an extra safety precaution, we recommend to contact the waste local services and/or the competent authorities in order to be properly informed about the disposal of the device.

The D.O.R.C. BrightStar Endo-illuminator complies with the international standard IEC60601-1 Class 1 type BF. WITH RESPECT TO ELECTRIC SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1/CAN/CSA C22.2 No. 601-1.

Label

This label is on the backside of the endo-illuminator. It measures 190mmx99mm.



Manufactured by:
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Exeter, NH 03833 Or : 603-778-6929
USA Fax : 603-778-0911
E-Mail : sales@dutchophthalmicusa.com

"This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation".

**Replacement lampmodule
is only available at
DORC International b.v.**

Icons used

The following icons are used in and on the D.O.R.C. Xenon BrightStar Endo-illuminator:



Attention, consult accompanying documents



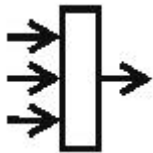
Caution: Dangerous voltage



Equipotential grounding connection



Dispose of equipment and parts properly



Optical Filter Selection



Type BF equipment



When lid: Lamp is ignited and ready for use

Rx Only US Federal law restricts this device to sale by on the order of a licensed physician only.



Protective Earth (Ground)



Alternating current



ON (Power: Connection to the mains)



OFF (Power: Disconnection from the mains)

Section 8 – Warnings

A warning indicates a potentially harmful situation to yourself or others.

Electric shock hazard

The D.O.R.C. BrightStar endo-illuminator contains high voltage circuits. After performing any repair, maintenance or calibration procedure, perform a final electrical safety check and leakage current test.

Unplug the power cord before cleaning or servicing the unit. Should the power cord or plug become cracked, frayed, broken or otherwise damaged, it should be replaced immediately.

Do not touch any exposed wiring or conductive surface, while the cover is off and the unit is energized. The voltages present, when electric power is connected to the D.O.R.C. BrightStar endo-illuminator, can cause injury or death.

Never forget to wear a grounding wrist strap when working on an opened unit. The operator should not perform any servicing except as specifically stated in the Instruction Manual.

Do not, under any circumstances, perform any testing or maintenance on medical instruments, while they are being used to monitor a patient. Always turn the D.O.R.C. BrightStar endo-illuminator OFF before cleaning.

Explosion hazard

Never use the D.O.R.C. BrightStar endo-illuminator in the presence of flammable aesthetics.

Electrostatic discharge through the printed circuit boards will damage the components of the D.O.R.C. BrightStar endo-illuminator. Handle all circuit boards (replacements and defective) by their non-conductive edges and use anti-static containers, when transporting them. Before servicing the equipment, ground yourself and the tool to discharge any accumulated static charge, by wearing a static tool wrist strap. Use hospital-grade grounded receptacle only.

Servicing of this products, in accordance with the Service Manual, should never be undertaken in the absence of proper tools, test equipment and the most recent revision of the Service Manual, which must be clearly and thoroughly understood.

Do NOT apply tension to the line cord. Check rear panel voltage setting before connecting the D.O.R.C. BrightStar endo-illuminator to AC main power.
NEVER IMMERSE THIS UNIT IN LIQUID !!!!

Section 9 – Electromagnetic Compatibility (EMC)

EMC between D.O.R.C. BrightStar endo-illuminator and other devices

It is important to install and use the equipment in accordance with the instruction in order to prevent interference with other devices in the vicinity. The D.O.R.C. BrightStar endo-illuminator complies with the safety requirements as described in the international standard: IEC 60601-1-2.

Changes or modifications which are not expressly approved by D.O.R.C. International b.v for compliance could void the user's authority to operate the equipment.



Cautions

- A caution indicates a condition that may lead to equipment damage or malfunction.
- Note that portable and mobile communication equipment can affect medical electrical equipment

Manufacturer's Declaration - Electromagnetic Emissions		
The Xenon BrightStar is intended for use in the electromagnetic environment specified below. The customer or the user of the Xenon BrightStar should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Xenon BrightStar uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Manufacturer's Declaration - Electromagnetic Immunity			
The Xenon BrightStar is intended for use in the electromagnetic environment specified below. The customer or the user of the Xenon BrightStar should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Xenon BrightStar requires continued operation during power mains interruptions, it is recommended that the Xenon BrightStar be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Manufacturer's Declaration - Electromagnetic Immunity			
The Xenon BrightStar is intended for use in the electromagnetic environment specified below. The customer or the user of the Xenon BrightStar should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Xenon BrightStar, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ 150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Xenon BrightStar is used exceeds the applicable RF compliance level above, the Xenon BrightStar should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Xenon BrightStar. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Xenon BrightStar			
The Xenon BrightStar is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Xenon BrightStar can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Xenon BrightStar as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.33\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,2	1,2	2,3
10	3,7	3,7	7,4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

FCC Regulations statement

This device has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and the receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Section 10 – Warranty

D.O.R.C. International b.v. warrants that all possible care was used in the choice of materials and manufacture of its products.

The D.O.R.C. International b.v. warranty will not be valid in case non-original D.O.R.C. accessories and/or spare parts are used !

D.O.R.C. International b.v. shall not be liable for any incidental or consequential loss, damage or expense, arising from abuse of its products. However, if D.O.R.C. International b.v.'s investigation shows that its products were defective at the time of shipment by D.O.R.C. International b.v., products will be replaced/repared at no charge.

Otherwise all D.O.R.C. International b.v. equipment is covered with a full year warranty, which does not cover the accessories.

D.O.R.C. International b.v. neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with its products.

Section 11 – Accessories

The following table presents the D.O.R.C. disposable sterile light fibers available for the BrightStar endo-illuminator. Per fiber type the recommended settings on the BrightStar and the maximum light output parameters are given.

Fiber	Filter	Recom- mended % Power	Max. % Power	Lumen (at 100% intensity and 435 filter)	ISO (at 100% intensity, 435 filter)
3269.AS	435nm	20	80	70	4,3
3269.ASB	435nm	20	80	65	1,6
3269.B	435nm	25	60	64	1,6
3269.B05	435nm	30	50	24	0,8
3269.B06	435nm	30	50	44	1,2
3269.D	435nm	20	80	70	4,2
3269.D05	435nm	30	60	40	2
3269.D06	435nm	25	60	44	2,8
3269.D1D	435nm	25	50	58	1
3269.E	435nm	20	50	65	1,6
3269.E06	435nm	30	50	44	1,2
3269.EB	435nm	25	50	65	1,6
3269.EB06	435nm	30	50	44	1,2
3269.EF	435nm	25	50	65	1,6
3269.MBD	435nm	25	50	65	1,6
3269.MBD2	435nm	50	100	44	1,2
3269.MBD27	435nm	50	100	42	1
3269.SB06	435nm	30	60	48	1,2
3272.EB	435nm	25	50	65	1,6
3286.ILB	435nm	30	50	44	1,2